

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

He the Application of: KOHNO, Naoyuki, et al.

Group Art Unit: 1645

Serial No.: 10/585,985

Examiner: Not Yet Assigned

Filed: July 13, 2006

P.T.O. Confirmation No.: 1712

For: PROTEIN IMMOBILIZATION METHOD AND QUANTIFICATION METHOD

## **LETTER**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Date: October 20, 2006

Sir:

The attention of the Patent and Trademark Office is hereby directed to a copy of the PCT Notification of Transmittal of Copies of Translation of the International Preliminary Report on Patentability attached herewith.

This Report is submitted herewith to be placed in the U.S. Patent and Trademark Office file of this case.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

Enclosure: PCT Notification of Transmittal of Copies of Translation of the International Preliminary Report on Patentability

#### PATENT COOPERATION TREATY

#### From the INTERNATIONAL BUREAU

## PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)

(PCT Rules 44bis.3(c) and 72.2)

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WAKO PURE CHEMICAL INDUSTRIES, LTD. 1-7, Nihonbashi-honcho 2-chome, Chuo-ku Tokyo 1030023 JAPON

Date of mailing (day/month/year) 31 August 2006 (31.08.2006)		
Applicant's or agent's file reference F1590WAKOPAT	IMPORTANT NOTIFICATION	
International application No. PCT/JP2005/000737	International filing date (day/month/year) 21 January 2005 (21.01.2005)	
Applicant WAKO PURE CHEI	MICAL INDUSTRIES, LTD. et al	

1.	Transmittal o	of the	translation	to	the a	pplicant.
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The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

### 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

#### None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

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## PATENT COOPERATION TREATY

# **PCT**

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference F1590WAKOPAT	FOR FURTHER ACTION	See item 4 below			
International application No. PCT/JP2005/000737	International filing date (day/month/year) 21 January 2005 (21.01.2005)	Priority date (day/month/year) 21 January 2004 (21.01.2004)			
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237					
Applicant WAKO PURE CHEMICAL INDUSTRIES, LTD.					

سيانانيس							
1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).						
2.	This REPORT consists of a total of 5 sheets, including this cover sheet.						
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.						
3.	This report contains indications	relating to the following	items:				
	Box No. I	Basis of the report					
	Box No. II	Priority					
	Box No. III	Non-establishment of applicability	f opinion with regard to novelty, inventive step and industrial				
	Box No. IV	Lack of unity of inve	ntion				
	Box No. V		ander Article 35(2) with regard to novelty, inventive step or industrial s and explanations supporting such statement				
	Box No. VI	Certain documents ci	ted .				
	Box No. VII	Certain defects in the	international application				
	Box No. VIII	Certain observations	on the international application				
4.	4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).						
	,						
			Date of issuance of this report 22 August 2006 (22.08.2006)				
	The International Bure 34, chemin des Col 1211 Geneva 20, Sv	ombettes	Authorized officer  Yoshiko Kuwahara				
	nile No. +41 22 338 82 70		e-mail: pt07@wipo.int				
Form F	PCT/IB/373 (January 2004)						

## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY			RITY	TANC.		
To:			·		PCT PCT TON	
5 5 5 5					RITTEN OPINION OF THE TIONAL SEARCHING AUTHORITY	
					(PCT Rule 43bis.1)	
				Date of mailing (day/month/year)		
Applica	ant's or agent's file rel	ference		FOR FURTHER	ACTION	
F15	90WAKOPAT				See paragraph 2 below	
	tional application No.		International filing date (	day/month/year)	Priority date (day/month/year) 21.01.2004	
Internat	tional Patent Classific	cation (IPC) or bot	h national classification and	d IPC		
Applica <b>WAK</b>		EMICAL II	NDUSTRIES, L'	TD.		
1.	This opinion contain	ins indications rela	ting to the following items			
				•		
	Box No. I	Basis of the	opinion			
	Box No. II Priority					
	Box No. III	Non-establi	shment of opinion with reg	ard to novelty, inventive step and industrial applicability		
	Box No. IV		ty of invention			
	Box No. V  Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement					
	Box No. VI		uments cited			
	Box No. VI		ects in the international app			
	Box No. VI	III Certain obse	ervations on the internation	al application		
2.	FURTHER ACTION	ON			·	
	International Prelimental than this one to be	ninary Examining the IPEA and the	Authority ("IPEA") except	that this does not ap the International Bu	ill be considered to be a written opinion of the oply where the applicant chooses an Authority other reau under Rule 66.1 bis(b) that written opinions of	
	written reply toget	her, where approp		before the expiration	A, the applicant is invited to submit to the IPEA a n of 3 months from the date of mailing of Form expires later.	
	For further options,	see Form PCT/IS.	A/220.			
3.	For further details,	see notes to Form	PCT/ISA/220.			
Name a	nd mailing address of	the ISA/IP		Authorized officer		
Allo al		10/11		Z LGCHOLIZOG UHICEL		
Facsimi	le No.			Telephone No.	·	

# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/000737

Bo	x No. I	Basis of this opinion
1.	With re	gard to the language, this opinion has been established on the basis of the international application in the language in which it was aless otherwise indicated under this item.
	T	his opinion has been established on the basis of a translation from the original language into the following language
		which is the language of a translation furnished for the purposes of international search (under
		ule 12.3 and 23.1(b)).
2.	With re invention	gard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed in this opinion has been established on the basis of:
	a. ty	pe of material
		a sequence listing
		table(s) related to the sequence listing
	b. fo	rmat of material
		in written format
		in computer readable form
	c. tin	ne of filing/furnishing
		contained in the international application as filed.
		filed together with the international application in computer readable form.
		furnished subsequently to this Authority for the purposes of search.
2	г¬ ,	
3.	tur	addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or nished, the required statements that the information in the subsequent or additional copies is identical to that in the application as ed or does not go beyond the application as filed, as appropriate, were furnished.
4.	Addition	al comments:

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/000737

Вох			ule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  pporting such statement	
l.	Statement			
	Novelty (N)	Claims	6, 11, 14-34	YES
		Claims	1-5, 7-10, 12, 13	NO
	Inventive step (IS)	Cłaims		YES
		Claims	1-34	NO
	Industrial applicability (IA)	Claims	1-34	YES
	·	Claims		NO

#### 2. Citations and explanations:

#### (Documents)

Document 1: Concaves, C.A. et. al., "Electrotransfer of fixed phosphoproteins from pieces of dried polyacrylamide gel to small disks of nitrocellulose, nylon or polyvinylidene difluoride" ELECTROPHORESIS, (1993), Vol. 14, No. 8, pages 789 to 793

Document 2: Jacobson, G. et al., "Important parameters in semi-dry electrophoretic transfer" ELECTROPHORESIS, (1990), Vol. 11, No. 1, pages 46 to 52

Document 3: Sheffield, J.B., et al., "A solid-phase method for the quantitation of protein in the presence of sodium dodecyl sulfate and other interfering substances" ANALYTICAL BIOCHEMISTRY, (1987), Vol. 166, No.1, pages 49 to 54

Document 4: Yamaguchi, K. et al., "Immunostaining method of isoferritins separated by isoelectric focusing on cellulose acetate membrane" JAPANESE JOURNAL OF ELECTROPHORESIS, (1991), Vol. 35, No. 4, pages 275 to 277

Document 5: JP, 58-205855, A (Tokyo Biochemical Research Foundation), 30 November, 1983 (30.11.83)

Document 6: JP, 2002-236127, A (Joko Co., Ltd.), 23 August, 2002 (23.08.02)

Document 7: WO, 02/057793, A2 (Baxter International Inc.), 25 July, 2002 (25.07.02) (Explanation)

#### 1. Concerning Novelty (Claims 1-5, 7-10, 12 and 13)

Documents 1 and 2 describe a method using a solvent containing SDS and methanol as a method for fixing a protein on a carrier such as nitrocellulose or PVCF for quantitative measurement by a method such as immunoblotting. Particularly, in document 2, a solution of 20% methanol and 0.1% SDS is used.

Accordingly, the subject matters of claims 1-5, 7-10, 12 and 13 do not appear to be novel.

#### 2. Concerning Inventive Step (Claims 6, 11 and 14-34)

Documents 3 and 4 describe that methanol is used for fixing a protein on a carrier such as nitrocellulose or PVDF. Documents 4-6 describe that trichloroacetic acid (TCA) that is a type of halogen carbonic acid is used for fixation of a protein.

Since methanol and trichloroacetic acid are reagents having similar functions, a person skilled in the art could easily use these reagents in combination. A person skilled in the art could

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/JP2005/000737

Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

accordingly set the amount of each reagent.

In the specification, comparison tests for various kinds of proteins are conducted for the resulting effects, but the carrier used is a PVDF film alone. In this point, it is common general technical knowledge that the fixation effect of the fixation reagent varies depending on the carrier used, but in the claims, it is only specified as a solid phase having a hydrophobic surface. Thus, carriers other than those using a film composed of nitrocellulose, PVDF or the like are not found to have a noticeable effect.

Thus, the subject matters of claims 6 and 11 do not appear to involve an inventive step.

Further, as described in document 7, a method of foxing an aberrant form prion protein and detecting/quantitatively measuring the protein by immunoblotting is known, and therefore a person skilled in the art could easily perform fixation and detection/quantitative measurement using the aforementioned mixed solvent. The effect thereof is not found to be noticeable except for effects for specific film carriers.

Thus the subject matters of claims 14-34 do not appear to involve an inventive step.

3. Industrial Applicability

The subject matters of claims 1-34 appear to be industrially applicable.